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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,191	07/30/2003	Richard D. Paoletti	DE-1495	9822

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EXAMINER

HUYNH, LOUIS K

ART UNIT

PAPER NUMBER

3721

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,191

Applicant(s)

PAOLETTI, RICHARD D.

Examiner

Louis K. Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, “a seal having a warning statement and other distinguishing characteristics” (claim 1) and “providing a seal with a warning statement and other distinguishing characteristics” (claim 13) are additional claimed limitations that are different from the “heat-shrink plastic cover” and thus constitute new matter. The invention of the present application is a safety seal comprising a heat-shrink plastic cover that forms the safety seal and bears a warning statement and other distinguishing characteristics. Thus, a safety seal comprising (1) a heat-shrink plastic cover and (2) a seal having a warning statement and other distinguishing characteristics is new matter which is not described in the originally filed specification and/or drawings.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4: "a seal having..." is new matter thus renders the claim indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8, 13-19, 21, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Key (US 6,385,878).

With respect to claim 1, Key discloses a safety seal comprising a heat-shrink plastic cover (100) that is adapted to be placed over a medicine container (130), wherein the heat-shrink plastic cover is provided with a written indicia (114) such as product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container.

With respect to claim 13, Key discloses a safety seal method including the steps of: placing a heat-shrink plastic cover (100) over a medicine container (130), and providing the heat-shrink plastic cover (100) with a written indicia (114) such as product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container.

With respect to claims 2 and 14, the heat-shrink plastic cover (100) is provided with a set of perforated line (116) (FIG. 3).

With respect to claims 3 and 15, Key teaches in another embodiment that the heat-shrink plastic cover (100) is provided with a set of perforated lines (704a, 704b) that are configured as a pull tab (FIG. 7).

With respect to claims 4 and 16, Key teaches in another embodiment that the heat-shrink plastic cover (100) is provided with a set of perforated lines (604a, 604b) that are configured as a tear strip (FIG. 6).

With respect to claims 5 and 17, the written indicia (114) can include product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container prior to removing the heat-shrink plastic cover (100).

With respect to claims 6 and 18, the heat-shrink plastic cover (100) includes visual cues such as the written indicia (114) and tactile awareness such as the texture of the heat-shrink plastic cover and/or the edge of the heat-shrink plastic cover disposed on top of the medicine container closure.

With respect to claims 7, 8, 19 and 21, the container (130) is a vial and is configured as a bottle shaped container.

With respect to claims 11 and 23, the heat-shrink plastic cover (100) covers the medicine container's mouth as shown in FIGS. 3, 6, and 7.

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With respect to claims 12 and 24, the texture of the heat-shrink plastic cover and/or the edge of the heat-shrink plastic cover would provide a tactile awareness of the heat-shrink plastic cover being in place.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Key (US 6,385,878).

The method and the heat-shrink plastic cover of Key meets all of applicants claimed subject matter but lack the specific teaching of the medicine container being configured as an intravenous bag. However, intravenous is a solution to be administered in to living body and thus the intravenous bag having outlet port that must be labeled with written indicia and must be protected from tampering; therefore, it would have been obvious to a skilled person in the art, at the time of the invention, to have modified the method of Key by having placed the heat-shrink plastic cover over an intravenous bag having outlet port, as required, so that the user can be informed of the integrity of the intravenous bag prior to usage.

8. Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Key (US 6,385,878) in view of Novice et al. (US 5,205,827).

The method and the heat-shrink plastic cover of Key meets all of applicants claimed subject matter but lack the specific teaching of the medicine container being configured as a syringe. However, Novacek teaches that medical syringe must be protected in a sterile condition such as wrapping the syringe with heat-shrink plastic cover (308) that serve as a tamperproof (FIG. 55) and assist in maintaining the sterility of the syringe (col. 28, line 56 – col. 29, line 8). Therefore, it would have been obvious to a skilled person in the art, at the time of the invention, to have modified the method of Key by having placed the heat-shrink plastic cover over a syringe, as taught by Novacek, in order to provide tamperproof and to assist in maintaining the sterility of the syringe.

Response to Arguments

9. Applicant's arguments filed 03/06/2006 have been fully considered but they are not persuasive.

Applicant contends that the reference to Key (US 6,385,878) does not address providing multiple alerts visual, tactile and functional to the provider in the process of medication administration and drawing the provider's special attention to these products. This is not found persuasive because the safety seal of Key having written indicia (114) such as product name, ingredient or direction for use, which alerts and enables the user to distinguish the medicine in the container from other medicine in a different container, and thus the safety seal of Key satisfies all of the claimed limitation.

Applicant further contends that the reference to Key does not disclose or suggest tactile awareness or enforcing function to help identify the product in and the prevention of hand medication errors. This is not found persuasive because the heat-shrink plastic cover (100)

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provides tactile awareness, and the written indicia (114) provides enforcing function to help identify the product.

Applicant further contends that the reference to Key does not disclose or suggest injectable vial containers, syringes or infusion bags as these products have tamper-evident closures so one skilled in the art would not have used the system in Key as it would not have been necessary for these products. This not found persuasive because it is known that syringes and/or intravenous bag must be protected from tampering; therefore, it would have been obvious to a skilled person in the art, at the time of the invention, to have protected syringes and/or intravenous bags from tampering using the safety seal system of Key.

Applicant further contends that the recited pull tab of the claimed invention is not disclosed or suggested in the patent to Key where instead perforated lines aid in the removal of the seal, and that the pull tab of the claimed invention is necessary to facilitate removal as an extra safety enhancement as caregivers may need these medications immediately in critical situations. This is not found persuasive because Key does disclose a release tab (708) in conjunction with the perforated lines (704a, 704b) to form an easy open feature for the safety seal (100).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

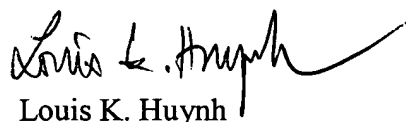
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is 571-272-4462. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louis K. Huynh
Primary Examiner
Art Unit 3721

April 11, 2006